

CLAIMS

1. A decellularized tissue comprising a biocompatible macromolecule.
2. A decellularized tissue according to Claim 1, wherein:
 - a) a cell residual rate of the tissue is less than a level at which an immune reaction is elicited in an organism; and
 - b) the tissue is not damaged to such an extent that hinders the tissue from exhibiting a function which was possessed by the tissue when the tissue was not decellularized.
3. A decellularized tissue according to Claim 1, wherein the biocompatible macromolecule coats the tissue.
4. A decellularized tissue according to Claim 1, wherein the biocompatible macromolecule is crosslinked with the tissue.
5. A decellularized tissue according to Claim 1, wherein the biocompatible macromolecule is crosslinked with the tissue by means of a radical reaction.
6. A decellularized tissue according to Claim 1, wherein the biocompatible macromolecule is crosslinked with a irradiation selected from the group consisting of ultraviolet irradiation, exposure to a free radical source, ultrasonication, x-ray irradiation, gamma-ray irradiation and electron beam irradiation.

7. A decellularized tissue according to Claim 1, wherein the biocompatible macromolecule is biodegradable.
8. A decellularized tissue according to Claim 1, wherein the biocompatible macromolecule comprises a macromolecule selected from the group consisting of polyvinyl alcohol (PVA), polyvinyl pyrrolidone (PVP), elastin, polyethylene glycol (PEG), gelatin, collagen, gamma-polyglutamic acid, and a mixture of the two or more thereof.
9. A decellularized tissue according to Claim 1, wherein the biocompatible macromolecule comprises polyvinyl alcohol or polyvinyl pyrrolidone.
10. A decellularized tissue according to Claim 1, wherein the polyvinyl alcohol is in the range of molecular weight of 500 to 200,000.
11. A decellularized tissue according to Claim 1, wherein the cell residual rate of the tissue is 30% or less.
12. A decellularized tissue according to Claim 1, wherein the tissue damage rate of the tissue is 30% or less.
13. A decellularized tissue according to Claim 1, wherein the tissue has a tissue strength which permits a clinical application.

14. A decellularized tissue according to claim 1, wherein the tissue has a tissue strength which is 80% or more of a tissue strength which was possessed by the tissue when the tissue was not decellularized.

15. A decellularized tissue according to claim 1, wherein the tissue has a tissue strength having a β value which is 80% or more of a β value which was possessed by the tissue when the tissue was not decellularized.

16. A decellularized tissue according to claim 1, wherein the tissue has a tissue strength having a β value of 20 or more.

17. A decellularized tissue according to claim 1, wherein the tissue is membranous, valvular, or luminal tissue.

18. A decellularized tissue according to claim 1, wherein the tissue is tissue selected from blood vessels, blood vessel-like tissue, cardiac valves, pericardia, dura matter, corneas, and bones.

19. A decellularized tissue according to claim 1, wherein a state of the tissue, in which the tissue is not damaged to such an extent that hinders the tissue from exhibiting a function which was possessed by the tissue when the tissue was not decellularized, includes that an extracellular matrix of the tissue is not substantially degenerated.

20. A decellularized tissue according to claim 18, wherein a survival rate of the extracellular matrix is at least about 50%.

21. A decellularized tissue according to claim 1, wherein the tissue is derived from a mammal.

22. A decellularized tissue according to claim 1, wherein the tissue is derived from a human or a swine.

23. A tissue graft comprising decellularized tissue according to Claim 1.

24. A tissue graft according to Claim 23, further comprising a cell.

25. A tissue graft according to Claim 23, wherein the tissue graft is free of a cell.

26. A tissue graft according to Claim 23, wherein the tissue graft has a form of selected from the group consisting of membranous, valvular, or luminal form.

27. A method of producing decellularized tissue, comprising the steps of:

- 1) providing tissue; and
- 2) decellularizing the tissue; and
- 3) exposing the tissue to a biocompatible macromolecule.

28. A method according to Claim 27, wherein the step of decellularizing comprises immersing the tissue in a solution containing a non-micellar amphiphatic molecule or a solution containing a surfactant.

29. A method according to Claim 27, wherein the step of exposing the tissue to a biocompatible macromolecule comprises crosslinking the biocompatible macromolecule.

30. A method according to Claim 29, wherein the crosslinking comprises a radical reaction.

31. A method according to Claim 29, wherein the radical reaction comprises a irradiation selected from the group consisting of ultraviolet irradiation, exposure to a free radical source, ultrasonication, x-ray irradiation, gamma-ray irradiation and electron beam irradiation.

32. A method according to Claim 29, wherein the radical reaction is gamma-ray irradiation.

33. A method according to Claim 32, wherein the irradiation dose of the gamma-ray irradiation is in the range of 10-300 kGy.

34. A method according to Claim 32, wherein the gamma-irradiation is conducted under a circumstance selected from the group consisting of in vacuum, in oxygen, in

nitrogen, in the air, in water, in an amphipathic molecule solution and a combination thereof.

35. A method according to Claim 32, wherein the gamma-irradiation is conducted for between 0.5-240 hours.

36. A method according to Claim 27, wherein the biocompatible macromolecule is biodegradable.

37. A method according to Claim 27, wherein the biocompatible macromolecule comprises a macromolecule selected from the group consisting of polyvinyl alcohol (PVA), polyvinyl pyrrolidone (PVP), elastin, polyethylene glycol (PEG), gelatin, collagen, gamma-polyglutaminic acid, and a mixture of the two or more thereof.

38. A method according to Claim 27, wherein the biocompatible macromolecule comprises polyvinyl alcohol or polyvinyl pyrrolidone.

39. A method according to Claim 38, wherein the polyvinyl alcohol is in the range of molecular weight of 500 to 200,000.

40. A method according to Claim 27, wherein the biocompatible macromolecule is used at the concentration between 1 w/v% to 50 w/v%.

41. A method according to Claim 28, wherein the amphipathic molecule is a 1,2-epoxide polymer.

42. A method according to Claim 28, wherein the amphipathic molecule is polyethylene glycol (PEG).

43. A method according to Claim 27, wherein the decellularization step is performed for 30 min to 10 days.

44. A method according to Claim 27, wherein the amphipathic molecule is biocompatible.

45. A method according to Claim 27, wherein the tissue is tissue selected from blood vessels, blood vessel-like tissue, cardiac valves, pericardia, dura matter, corneas, and bones.

46. A method according to Claim 27, wherein the tissue is derived from a mammal.

47. A method according to Claim 27, wherein the tissue is derived from a human or a swine.

48. A method according to Claim 27, further comprising the step of a chemical treatment which is a nuclease treatment.

49. A method according to Claim 48, wherein the chemical treatment comprises a treatment by means of DNase.

50. A decellularized tissue obtainable by a method according to Claim 27.

51. A method for regenerating a tissue, comprising the steps of:

- a) providing decellularized tissue comprising a biocompatible macromolecule into an organism; and
- b) incubating the tissue within the organism for a time sufficient for the tissue to regenerate.

52. A method according to claim 51, further comprising providing a cell to the decellularized tissue.

53. A method according to claim 51, further comprising providing a physiologically active substance which induces cellular differentiation, to the organism.

54. A method according to claim 53, wherein the physiologically active substance is from the organism or from outside the organism.

55. A method according to claim 52, wherein the physiologically active substance is provided in a form of nucleic acid or polypeptide form.

56. A method according to claim 53, wherein the physiologically active substance is selected from the group consisting of HGF, VEGF, FGF, IGF, PDGF and EGF.

57. A method according to claim 51, wherein the tissue is tissue selected from blood vessels, blood vessel-like tissue, cardiac valves, pericardia, dura mater, corneas, and bones.

58. A method for producing a tissue graft, comprising the steps of:

- a) providing decellularized tissue comprising a biocompatible macromolecule into an organism;
- b) allowing a self cell in the organism to infiltrate the decellularized tissue; and
- c) incubating the tissue within the organism for a time sufficient for the cell to differentiate.

59. A method according to Claim 58, wherein the tissue is tissue selected from blood vessels, blood vessel-like tissue, cardiac valves, pericardia, dura matter, corneas, and bones.

60. A method according to Claim 58, wherein the decellularized tissue is autologous.

61. A method according to Claim 58, wherein the decellularized tissue is derived from a homologous host.

62 A method according to claim 58, wherein the decellularized tissue is derived from a heterologous host.

63. A method according to Claim 58, further comprising the step of:

- providing a physiologically active substance which induces differentiation of the cell.

64. A method according to Claim 63, wherein the physiological active substance is a cytokine having hemopoietic activity.

65. A tissue graft produced by a method according to Claim 58.

66. A method of treating a subject requiring transplantation of tissue or an organ or treating a subject at a risk of transplantation of tissue or an organ for prophylaxis, the method comprising the steps of:

- providing decellularized tissue comprising a biocompatible macromolecule or a tissue graft comprising the decellularized tissue into an organism; and
- transplanting the decellularized tissue or tissue graft to a subject.

67. A method according to claim 66, wherein the tissue is derived from the subject.

68. A method according to claim 66, wherein the tissue is tissue selected from the group consisting of blood vessels, blood vessel-like tissue, cardiac valves, pericardia, dura matter, corneas, and bones.

69. A method according to claim 66, wherein the subject is a mammal.

70. A method according to claim 66, wherein the subject is a human.

71. A pharmaceutical for organ transplantation, comprising:
a) decellularized tissue comprising a biocompatible macromolecule or a tissue graft comprising the decellularized tissue into an organism.

72. A pharmaceutical according to claim 71, wherein the tissue is tissue selected from the group consisting of blood vessels, blood vessel-like tissue, cardiac valves, pericardia, dura matter, corneas, and bones.

73. A pharmaceutical according to claim 71, wherein the cell is derived from a mammal.

74. A pharmaceutical according to claim 71, wherein the tissue is derived from a human.

75. A pharmaceutical according to claim 71, wherein the tissue is derived from the subject requiring transplantation.

76. Use of decellularized tissue comprising a biocompatible macromolecule or a tissue graft comprising the decellularized tissue for manufacture of a pharmaceutical for organ transplantation.